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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,914	07/03/2003	Jerome P. Horwitz	1319.007US1	4646
7590 02/02/2005 Schwegman, Lundberg, Woessner & Kluth, P.A. P.O. Box 2938 Minneapolis, MN 55402			EXAMINER QAZI, SABIHA NAIM	
			ART UNIT 1616	PAPER NUMBER

DATE MAILED: 02/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/613,914	<b>Applicant(s)</b> HORWITZ ET AL.	
	<b>Examiner</b> Sabiha Qazi	<b>Art Unit</b> 1616	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 03 July 2003.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 31-48 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-30 is/are allowed.
- 6) ☒ Claim(s) 59-64 is/are rejected.
- 7) ☒ Claim(s) 49-58 is/are objected to.
- 8) ☒ Claim(s) 31-48 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |  |
|---|--|
| <p>1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)</p> <p>2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)</p> <p>3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br/>Paper No(s)/Mail Date _____</p> | <p>4) <input type="checkbox"/> Interview Summary (PTO-413)<br/>Paper No(s)/Mail Date. _____</p> <p>5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)</p> <p>6) <input type="checkbox"/> Other: _____</p> |
|---|--|

**Non-Final Office Action**

Claims 1-64 are pending. Claims 1-30 are allowed. Claims 49-58 are objected to for containing non-elected subject matter.

**Election/Restrictions**

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-30, and 49-64 (in part) drawn to a compound of Formula I, their compositions, and methods of use, (when A represents CH) classified in class 546, subclass 157 and class 514, subclass varies.
- II. Claims 31-48 and 49-64 (in part), drawn to a compound of Formula I, their compositions, and methods of use, (when A represents N) classified in class 544, subclass 354 and class 514, subclass varies.

These inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. These inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper. These inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with William F. Prout on November 12, 2004 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-30. Applicant in replying to this Office action must make affirmation of this election. Claims 31-64

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withdrawn (in-part, when A represents N) from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

### **Claim Rejections - 35 USC § 101**

35 U.S.C. 101 reads as follows:

*Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.*

Claim 60 is rejected under 35 U.S.C. 101 because claimed invention is directed to nonstatutory subject matter. Claims 60 is drafted in terms of “use”, however “use” is not one of the statutory classes of invention. Clinical Products v. Brenner, 1449 USPQ 475, 476 (1966).

Examiner suggests that the Applicants redraft the claim to accord with current US practice.

### **Claim Rejections - 35 USC § 112 – First Paragraph**

The following is a quotation of the first paragraph of 35 U.S.C. 112:

*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

Claims 59 and 61-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific cancers tested against in the specification, does not reasonably provide enablement for the treatment of all cancers. Evidence involving a single compound and two types of cancer was not found sufficient to establish the enablement of claims directed to a method of treating seven types of cancer with members of a class of several compounds. In re Buting, 163 USPQ 689. The disclosure provides no indication of whether the compounds treat all cancers. To make clearer the lack of enablement for treatment of all cancer, extrinsic evidence is supplied by Draetta (Ann. Reports Med. Chem.), Draetta et al. in "Annual Reports in Medicinal Chemistry", 1996, Academic Press, San Diego, pp 241-246, final sentence on page 246 although many still think about the need for a magic bullet as a cure for all cancers, our knowledge of the molecular mechanism underlying this disease make the prospect of developing such a universal cure very unlikely." Since no universal cure for cancer has been developed, it follows that there is no correlation between the assays relied upon by applicants and the ability to treat all cancers. Thus, those assays are not sufficient to enable such claims.

Further, in the art of clinical oncology, no compound has yet shown clinical efficacy against every type of cancer. To quote Salmon (Principles of Cancer Therapy) in the paragraph on page 1038 titled "Medical Therapy", palliative therapy has been developed for a series of relatively uncommon neoplasms and useful palliative therapy has been developed for some common forms of cancer (Table 162-4). With rare exceptions, effective therapy has utilized, combinations of anticancer drugs." Applicant's attention is drawn to Tables 162-6, 162-7, 162-8, 162-9, 162-10, and the material on pages 1045-1046 titled "Miscellaneous Anticancer Agents" in Salmon (Principles of Cancer Therapy). Different agents are used for different forms of cancer

and no single agent is listed as a treatment of every single type of cancer. To quote Balasubramanian (Recent Developments in Cancer Cytotoxics) from page 151 first paragraph “the successful treatment of solid tumors remains a formidable challenge.”

Applicant has provided no evidence which incontrovertibly demonstrates that the tests set forth in the instant specification are art-recognized, reliable predictors of successful treatable, in vivo, of all cancers.. The worker of ordinary skill in the art would not be able to practice the instantly claimed method, since no description is found of an actual method wherein a cancer in a host is treated. Applicants fail to fulfill the requirement of 35 U.S.C. 112, first paragraph, by failing to provide an adequate written description of how to treat all cancers in a single host.

#### **Claim Rejections - 35 USC § 112 – Second Paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

Claim 59 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What is intended by the term “medical therapy”? A clarification is requested.

#### ***Allowable Subject Matter***

1. Claims 1-30 are allowed. Prior art of record does not teach nor fairly suggests the compounds of formula (I) when A represents C atom.

2. Claims 49-58 are objected to for containing non elected subject matter.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sabiha Qazi whose telephone number is (571) 272-0622. The examiner can normally be reached on any business day.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



SABIHA QAZI, PH.D  
PRIMARY EXAMINER

Saturday, December 4, 2004